REMARKS

Claims 1-14 have been cancelled by this amendment. New claims 49-57 have been added. Accordingly, claims 49-57 are pending in this application. Reconsideration is respectfully requested.

THE INVENTION

Applicants have surprisingly discovered a novel composition comprising a glycoprotein matrix bound to coenzyme Q10 (coQ10). The composition is obtained by fermenting yeast, bacteria, or both, in the presence of the coQ10. According to the invention, the yeast, bacteria or both produce the glycoprotein matrix. In addition, the yeast and bacteria are suitable for consumption by mammals. As a result of the fermentation, the glycoprotein matrix that is produced binds to the coQ10.

Because the glycoprotein matrix is bound to the coQ10, the claimed composition possesses improved properties when compared to conventional coQ10 compositions (e.g. admixtures). For example, the claimed composition has increased stability when compared to conventional coQ10 compositions. See Example 3 and Table 2 of the application.

Importantly, the claimed composition has increased bioactivity. For instance, in Example 2 and Table 1 of the application, coenzyme Q10 bound by a glycoprotein matrix demonstrates antioxidant activity that is 20 times greater than commercially available (e.g. unbound) coenzyme Q10.

REJECTIONS UNDER 35 U.S.C. §112

Claims 1-14 have been rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabled. On page 2 of the Office Action, the Examiner contends that the specification "does not reasonably provide enablement for a composition of glycoproteins bound to a ubiquinone," and that "no chemical reaction steps are detailed which would teach one in the art how to generically bind a glycoprotein to a ubiquinone." Applicant respectfully disagrees.

The specification on page 7, lines 14-23 states:

> ...the glycoprotein matrix can be bound to the ubiquinone by allowing the microorganism to ferment, in the presence of the ubiquinone. As used herein, fermentation is the process by which microorganisms metabolize raw materials, such as amino acids and carbohydrate, to produce glycoprotein. .... The glycoprotein from the microorganism that forms the glycoprotein matrix is mainly extracellular and, therefore, is available to be bound to ubiquinone.

In a sincere effort to more clearly define the scope of the claims, Applicant has cancelled claims 1-14 and added new claims 49-57. The new claims recite a composition comprising a glycoprotein matrix bound to coQ10 that is obtained by fermenting yeast, bacteria, or both, in the presence of the coQ10. Support for the new

claims can be found on page 7, lines 14-23 of the application which are reproduced above.

As discussed in the above excerpt of the specification, and reflected in the new claims, the coQ10 is bound by the glycoprotein matrix as a result of the fermentation process with microorganisms (i.e. yeast, bacteria, or both). Aside from the fermentation step, "no chemical reaction steps" are necessary to accomplish binding of the glycoprotein to the coQ10, in the claimed invention.

Accordingly, Applicant respectfully submits that the claims enable a person skilled in the art to make the invention commensurate in scope with the new claims. Hence, Applicant respectfully requests that the rejection under 35 U.S.C. §112, first paragraph be reconsidered and withdrawn.

Claims 1-14 have been rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. The Examiner contends that claim 1, and the dependent claims, are rendered vague and indefinite for reciting "bound to." Applicant respectfully traverses this rejection.

According to the Examiner, "the specification does not clearly convey how the glycoprotein is bound as there is no positive recitation of a binding step..." As discussed above, new claims 49-57 have been added which recite the process by which the binding occurs. Furthermore, page 6, lines 14-15 of the specification states

that the glycoprotein matrix molecules are believed to be bound to the ubiquinone molecules by weak covalent bonds.

Accordingly, in view of the above discussion and newly presented claims, Applicants submit that the rejection based on §112, second paragraph be reconsidered and withdrawn.

Lastly, claim 2 was rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for reciting "CoQ_{10}" because the term is not first written out, followed by the abbreviation.

In response, Applicants have cancelled claim 2 and added new claims which do not contain an abbreviation. Accordingly, the rejection of claim 2 under §112, second paragraph has been rendered moot.

REJECTIONS UNDER 35 U.S.C. §102

Claims 1 and 14 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,565,558 to McCully. On page 4 of the office action, the Examiner alleges that "McCully teaches compositions for treating and preventing neoplastic, atherosclerotic, viral, and degenerative diseases wherein substances such as ubiquinone, tumor necrosis factor, erythropoietin, colony stimulating factor and granulocyte macrophage stimulating factor are administered." The Examiner

contends the claimed invention is anticipated by McCully. Applicant respectfully disagrees.

McCully teaches the administration of thioretinaco ozonide in combination with interferons alpha, beta, or gamma (col. 5, lines 26-27). McCully discloses that interferon can be replaced with other classes of "membranergic substances," such as ubiquinone, cytokines, polypeptide growth factors, etc. (col. 6, lines 6-28). Within each such class, exist numerous species to choose from.

The claimed invention is for a specific composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix.

According to McCully, only one (ubiquinone) or none of the components of the claimed invention need be present. Moreover, McCully does not disclose a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both produce the glycoprotein matrix. Therefore, McCully does not anticipate the present invention.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on McCully be withdrawn.

Claims 1 and 14 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,298,246 to Yano et al. The Examiner alleges that Yano et al. teach compositions comprising ubiquinones and bioactive peptides such as erythropoietin, colony stimulating factor, protein C, tumor necrosis factor, lactoferrin, transferrin, and immunoglobulins. The Examiner contends the claimed invention is anticipated by Yano et al. Applicant respectfully disagrees.

Yano et al. disclose the emulsification of a lipophilic drug using a fat globule membrane derived from mammalian milk (see column 4, lines 42-45). Yano et al. mention ubiquinone as an example of a lipophilic drug (see column 3, lines 57-62).

As discussed above, the present invention is a composition comprising a glycoprotein matrix bound to coQ10, wherein the glycoprotein matrix is obtained by fermenting a yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix.

Nowhere in Yano et al. is there disclosure of fermenting a yeast, bacteria, or both, to produce a glycoprotein matrix, in the presence of coQ10. Therefore, Yano et al. do not anticipate the present invention.

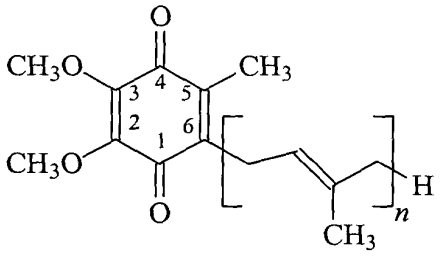
Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Yano et al. be withdrawn.

Claims 1-2 and 14 have been rejected under 35 U.S.C. §102(a) as being anticipated by JP 2000281586 A to Toba et al. The Examiner alleges that Toba et al. teaches bone-strengthening compositions comprising lactoferrin and vitamin K. The Examiner contends that vitamin K is ubiquinone, and that the claimed invention is anticipated by Toba et al. Applicant respectfully disagrees.

Toba discloses a bone strengthening agent containing an iron lactoferrin. According to Toba, the bone strengthening agent can be compounded with a component contributing to bone metabolism such as calcium, magnesium, vitamin D, vitamin K or an oligo sugar.

The present invention is a composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix. Nowhere in Toba et al. is there any disclosure of a glycoprotein matrix bound to coQ10 obtained in accordance with the present invention.

Furthermore, Toba et al. do not disclose coQ10. Co Q10 is a species of ubiquinone (n=10). Applicant respectfully disagrees with the Examiner's characterization of vitamin K being synonymous with ubiquinone. On page 5 of the application, the chemical structure of ubiquinone is provided, as follows:



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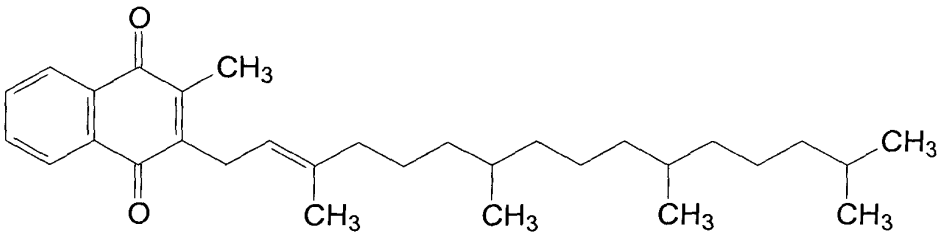
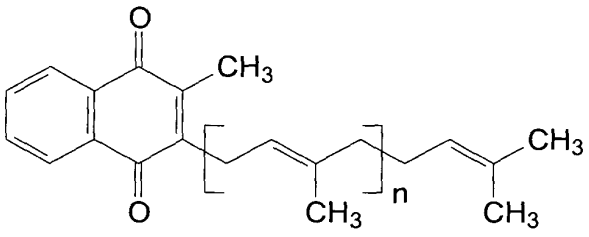
wherein typically n = 1-12, preferably n = 6-12, and most preferably n = 10 (coenzyme Q10).

The chemical structure of vitamin K, and its derivatives, is different. For example, vitamin K is a bicyclic structure. See below:

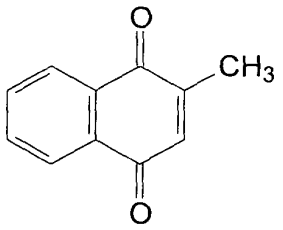
Vitamin K1



Vitamin K2



Vitamin K3



Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(a) based on Toba et al. be withdrawn.

Claims 1-2 and 14 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,804,555 to Tomita et al. According to the Examiner, Tomita et al. teach antioxidant compositions comprising lactoferrin hydrosylates and coenzyme Q, and therefore, the Examiner contends that the claimed invention is anticipated. Applicant respectfully disagrees.

Tomita et al. teach combining selected peptides derived from lactoferrin hydrosylates with an oxidation preventative agent. Tomita et al. provide examples of oxidation preventative agents, including vitamin E, vitamin C, vitamin A, β-carotene, superoxide dismutase, and coenzyme Q (col. 3, lines 36-43).

In contrast, as discussed above, the present invention is a composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix. Nowhere in Tomita et al. is there any disclosure of a

glycoprotein matrix bound to coQ10 obtained in accordance with the present invention.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Tomita et al. be reconsidered and withdrawn.

Claims 1-5, 8-9, and 14 have been rejected under 35 U.S.C. §102(b) as being anticipated by GB 2178622 A to Seuref. The Examiner alleges that Seuref teaches compositions of coenzyme Q and brewer's yeast. The Examiner contends that although Seuref does not teach that Q10 is bound to a glycoprotein, the manner of obtaining the compositions of Seuref is the same as that obtained by Applicant.

The Examiner goes on to allege that "it must be inherent to the compositions of Seuref that the ubiquinone and yeast are bound together as claimed by Applicant." Applicant respectfully disagrees.

Seuref merely discloses an admixture containing dry yeast extract and coenzyme Q. In contrast, the present invention utilizes active microorganism (e.g. yeast, bacteria or both).. Furthermore, in the claimed composition, a fermentation step is required in order to encourage the microorganisms to produce the glycoprotein matrix that eventually binds the coQ10.

In order to rely on the theory of inherency, "the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the

allegedly inherent characteristic necessarily flows from the teachings of the applied art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added in original).

As mentioned above, Seuref provides a dry yeast extract and coenzyme Q admixture. Seuref, however, does not teach a composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix. .

Consequently, the Examiner has not provided evidence that a composition comprising a glycoprotein matrix bound to a coQ10, obtained in accordance with the claims, would necessarily, or even possibly, flow from the teachings of Seuref.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Seuref be withdrawn.

Claims 1-2, 5, 8-10 and 14 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,658,648 to Nakao et al. The Examiner contends that "Nakao et al. teaches compositions of coenzyme Q10 wherein yeasts are fermented to produce coenzyme Q10."

The Examiner recognizes that Nakao et al. does not teach coenzyme Q10 bound to a glycoprotein. However, the Examiner asserts that the manner of obtaining

the disclosed compositions is the same as Applicant's. Based thereon, the Examiner alleges that in Nakao et al., it is inherent that ubiquinone and yeast glycoproteins are bound. Applicant respectfully disagrees.

Nakao et al. teach a method for the production of coenzyme Q under aerobic conditions and using a culture medium that requires water insoluble hydrocarbons containing C_9 to C_{23} paraffins. (see col. 3, lines 45-52). The aerobic conditions and culture medium required by Nakao et al. are specifically selected to encourage yeast to produce coenzyme Q.

Importantly, the microorganisms disclosed by Nakao et al. that produce the CoQ10 (Pseudomonas denitrificans and Neurospora crassa) are not suitable for consumption by mammals. (see column 1, lines 42-43 of Nakao et al.)

The present invention utilizes a fermentation process to encourage microorganisms to produce a glycoprotein matrix that will bind to the coQ10. Unlike aerobic processes (i.e. requiring oxygen), fermentation requires no, or very little, oxygen.

Furthermore, as indicated in the new claims, the microorganisms of the claimed invention must be suitable for consumption by mammals.

As mentioned above, in order to rely on the theory of inherency, "the Examiner must provide a basis in fact and/or technical reasoning to reasonably

support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added in original).

Nakao et al. provide a method for encouraging microorganisms (not suitable for consumption) to produce coenzyme Q under aerobic conditions. Nakao, et al., however, do not teach a composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria or both (that are suitable for consumption) in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix.

Consequently, the Examiner has not provided evidence that a composition comprising a glycoprotein matrix bound to a coQ10, obtained in accordance with the claims, would necessarily, or even possibly, flow from the teachings of Nakao et al.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Nakao et al. be withdrawn.

Claims 1-2, 5-7 and 12 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,895,652 to Giampapa. The Examiner alleges that Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, lipase and algae. The Examiner contends that the claimed invention is anticipated by Giampapa. Applicant respectfully disagrees.

The present invention is a composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix.

Importantly, Giampapa does not disclose yeast or bacteria, or a fermentation process, as in the claimed invention. Giampapa does not disclose a glycoprotein matrix bound to coQ10 obtained in accordance with the present invention. Therefore Giampapa cannot be found to anticipate the present invention.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Giampapa be withdrawn.

Claims 1-2, 5, 8-10 and 13-14 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,306,453 to Kurzinger. The Examiner alleges that Kurzinger teaches compositions comprising vitamin K and one or more immunostimulators, including lactoferrin, extracts of bacteria and extracts of *Saccharomyces cerevisiae*. The Examiner alleges that vitamin K is a ubiquinone. Therefore, the Examiner contends that Kurzinger anticipates the claimed invention.

Kurzinger teaches an anti-stress feed for aquatic animals. The feed requires an immunostimulating agent and vitamin A or vitamin K.

In stark contrast, the present invention is a composition comprising a glycoprotein matrix bound to coQ10 obtained by fermenting yeast, bacteria, or both,

in the presence of coQ10. Kurzinger does not disclose the present invention. Furthermore, as discussed above, vitamin K is not a ubiquinone, and definitely not synonymous with coQ10..

Thus, Kurzinger does not anticipate the present invention, and Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Kurzinger be withdrawn.

REJECTIONS UNDER 35 U.S.C. §103

Claims 1-4 and 14 have been rejected under 35 U.S.C §103(a) as being unpatentable over Toba. According to the Examiner, Toba teaches bone-strengthening compositions comprising lactoferrin and vitamin K. The Examiner alleges that vitamin K is a ubiquinone.

The Examiner recognizes that Toba does not teach the ratio of glycoprotein to coenzyme Q10 as taught in the present invention. However, the Examiner alleges it would have been obvious to one of ordinary skill to optimize such ratios. Applicants respectfully disagree.

As mentioned above, Toba does not disclose or suggest a composition comprising coQ10 and a glycoprotein obtained by fermenting yeast, bacteria or both in the presence of coQ10, wherein the yeast, bacteria, or both, produce the glycoproteins that bind the coQ10.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of fermenting yeast, bacteria or both, in the presence of the coQ10, in order to promote the production of glycoproteins by the yeast, bacteria or both, and to encourage the binding of the coQ10 to the glycoproteins. Additionally, vitamin K is not synonymous with ubiquinone.

Toba does not teach or suggest all of the claimed limitations of the present invention. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Toba. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Toba be withdrawn.

Claims 1-5, 8-10 and 14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Nakao et al. Although the Examiner recognizes that Nakao et al. do not teach the amounts of coQ10 or the ratio of coQ10 to glycoprotein in the claimed invention, the Examiner alleges that it would have been obvious to one of ordinary skill to optimize such volumes. Applicant respectfully disagrees.

Nakao et al. do not teach the amounts of ubiquinone or the ratio of ubiquinone to glycoprotein as in the claimed invention because Nakao et al. are not adding

ubiquinone to a composition. Rather, as discussed above, Nakao et al. disclose a process for encouraging yeast to produce coenzyme Q under aerobic conditions.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of fermenting yeast, bacteria or both, in the presence of coQ10, in order to promote the production of glycoproteins by the yeast, bacteria or both, and to encourage the binding of the coQ10 to the glycoproteins.

Nakao et al. do not teach or suggest all of the claimed limitations of the present invention. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Nakao et al. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Nakao et al. be withdrawn.

Claims 1-7 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa. The Examiner recognizes that Giampapa fails to disclose the volume or ratio of coenzyme Q10 to glycoprotein as in the claimed invention. However, the Examiner alleges that it would have been obvious to one of ordinary skill to optimize such ratios.

As discussed above, Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, lipase and algae. Giampapa does not disclose or suggest a composition comprising a glycoprotein matrix bound to coQ10 by a fermenting a yeast, bacteria, or both, in the presence of coQ10, wherein the yeast, bacteria, or both produce the glycoprotein matrix.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of fermenting yeast, bacteria or both, in the presence of coQ10, in order to promote the production of glycoproteins by the yeast, bacteria or both, and to encourage the binding of the coQ10 to the glycoproteins.

Giampapa do not teach or suggest all of the claimed limitations of the present invention. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Giampapa. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Giampapa be withdrawn.

Claims 1-5, 8-10 and 13-14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kurzinger. The Examiner recognizes that Kurzinger do not disclose the volume or ratio of coenzyme Q10 to glycoprotein as in the claimed

invention. However, the Examiner alleges that it would have been obvious to one of ordinary skill to optimize such ratios.

As stated above, Kurzinger merely teaches an anti-stress feed for aquatic animals containing vitamin K. Kurzinger does not disclose or suggest a composition comprising a glycoprotein matrix bound to coQ10 by a fermenting yeast, bacteria, or both, in the presence of coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of fermenting yeast, bacteria or both, in the presence of coQ10, in order to promote the production of glycoproteins by the yeast, bacteria or both, and to encourage the binding of the coQ10 to the glycoproteins.

Kurzinger do not teach or suggest all of the claimed limitations of the present invention. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Kurzinger. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Kurzinger be withdrawn.

Claims 1-5 and 10-12 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Metz (Derwent 1998-399777) and Kruzel (Derwent 1991-295636). Metz discloses a food supplement comprising various vitamins and among other ingredients, coenzyme Q10 and *E. coli* or *Lactobacillus acidophilus*. Kruzel discloses a recombinant human lactoferrin.

The Examiner recognizes that Metz and Kruzel do not disclose the ingredients in a single composition, but alleges that it would have been obvious to combine the ingredients of Metz and Kruzel to obtain the present invention.

Neither Metz nor Kruzel disclose or suggest a composition comprising a glycoprotein matrix bound to coQ10 by a fermenting yeast, bacteria, or both, in the presence of the coQ10, and wherein the yeast, bacteria, or both, produce the glycoprotein matrix.

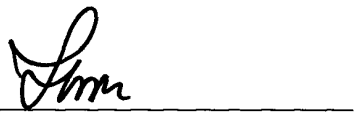
In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art references must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of fermenting yeast, bacteria or both, in the presence of coQ10, in order to promote the production of glycoproteins by the yeast, bacteria or both, and to encourage the binding of the coQ10 to the glycoproteins.

Upon combining the teachings of Metz and Kruzel, all of the claimed limitations of the present invention are neither disclosed nor suggested. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Metz and Kruzel. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Metz and Kruzel be withdrawn.

In light of the foregoing amendments and remarks, Applicant respectfully submits that the application is now in condition for allowance. If the Examiner believes a telephone discussion with the Applicant's representative would be of assistance, she is invited to contact the undersigned at her convenience.

Respectfully submitted,



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